UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF MISSOURI
EASTERN DIVISION

AIDS HEALTHCARE FOUNDATION, Plaintiff, vs. EXPRESS SCRIPTS, INC., Defendant	Cause No: 4:22-cv-00743 AGF **JURY TRIAL DEMANDED**

FIRST AMENDED COMPLAINT FOR DAMAGES AND INJUNCTIVE RELIEF

Plaintiff AIDS Healthcare Foundation ("AHF"), by and through its counsel of record, states the following for its First Amended Complaint against defendant Express Scripts, Inc. ("ESI"), seeking damages and injunctive relief.

NATURE OF THE ACTION

1. AHF, the owner of a chain of pharmacies serving primarily people of limited economic means living with HIV/AIDS, brings this civil action to recover many millions of dollars taken by ESI, in its capacity as a pharmacy benefits manager ("PBM"), purportedly pursuant to unconscionable contracts with AHF pertaining to so-called "performance programs" (the "Claw Back Programs") in violation of those very contracts and the covenant of good faith and fair dealing implied in those contracts, among other violations of AHF's rights, discussed more fully below.

PARTIES

2. Established in 1987, AHF is a California not-for-profit, public benefit, tax exempt, 501(c)(3) corporation, domiciled and with its principal place of business in Los Angeles, California. AHF is the world's largest provider of health care services to people living with HIV/AIDS and is the largest private-sector provider of HIV/AIDS medical care to people in the United States. AHF's mission is to provide cutting edge medical care to people living with HIV/AIDS regardless of their ability to pay, and AHF provides medical care (including prescription drugs services) and advocacy to more than 1.6 million patients in 45 countries, including the United States. AHF and owns and operates 62 retail, accredited, specialty pharmacies[1] in 14 states (California, Florida, Georgia, Illinois, Louisiana, Maryland, Mississippi, Nevada, New York, Ohio, Pennsylvania, South Carolina, Texas, and Washington) and 2 territories (Puerto Rico and the District of Columbia) that serve people living with HIV/AIDS, including patients enrolled in the Medicare Part D prescription drug program ("Part D"). In the United States, AHF operates 84 health care centers in 16 states, the District of Columbia and Puerto Rico. The great majority of AHF's patients and pharmacy customers are people living with HIV/AIDS with varying types of insurance coverage, including patients enrolled in

[1] AHF's pharmacies are accredited as specialty pharmacies by two respected accrediting entities, URAC and ACHC. Accredited specialty pharmacies have demonstrated superior proficiency handling specialty medications which require higher levels of monitoring and patient education.

the Part D prescription drug program. AHF provides the vast majority of care for free to people without means of paying for it, and to people of limited means who rely on government programs such as Medicaid, Medicare, and the Ryan White CARE Act to pay for care. AHF is an essential safety net provider for disenfranchised, high-risk populations.

3. AHF is informed and believes and, based thereon, alleges as follows: ESI is a Delaware corporation, which is a wholly-owned subsidiary of Cigna Corporation (also a Delaware corporation), an international health services corporation with an adjusted revenue of $174 billion in 2021.[2] On December 20, 2018, Cigna acquired ESI, then the nation's largest PBM, for $67 billion.[3] ESI currently manages drug benefits for more than 80 million Americans, including those enrolled in union-sponsored plans, state employee health plans, and public purchasers.[4] Over 67,000 retail pharmacies across the United States participate in

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[2] CIGNA 2021 Annual Report, p. 3, https://s27.q4cdn.com/742843823/files/doc_financials/2021/ar/2021-Annual-Report.pdf (last accessed September 30, 2022).

[3] Joe Cooper, "Cigna Closes $67B Express Scripts Purchase," HARTFORD BUSINESS (Dec. 20, 2018), https://www.hartfordbusiness.com/article/cigna-closes-67b-express-scripts-purchase (last accessed September 30, 2022); see also Cigna Corp., Annual Report (10-k) (Feb. 28, 2019). https://d18rn0p25nwr6d.cloudfront.net/CIK-0001739940/5b5eb8e1-6da1-4058-b12e-0f6ee3a9654f.pdf (last accessed September 30, 2022).

[4] Report from New York State Senate Committee on Investigations and Government Operations, May 31, 2019, citing, Response from Eric W. Sitarchuk on behalf of Express Scripts Inc., to the New York State Senate Investigations and Government Operations Committee (Feb. 27, 2019). https://www.nysenate.gov/sites/default/files/article/attachment/final_investigatory_report_pharmacy_benefit_managers_in_new_york.pdf (last accessed September 30, 2022).

one or more of ESI's contracted pharmacy benefit networks.[5] In 2017, ESI adjudicated over 877 million claims through those pharmacies.[6]

SUBJECT-MATTER JURISDICTION

4. This Court has subject matter jurisdiction over this civil action because the amount of money in controversy exceeds $75,000, exclusive of interest and costs, and AHF and ESI are citizens of different U.S. states. 28 U.S.C. § 1332.

5. This Court also has supplemental jurisdiction over that part of this civil action's subject matter that arises under state law, because that part is so related to the claims under federal law as to form part of the same case or controversy under Article III of the U.S. Constitution. 28 U.S.C. § 1367.

VENUE

6. This judicial district is the proper venue for this civil action, because (a) ESI resides, is found, is headquartered, and conducts business within this judicial district; (b) ESI is subject to personal jurisdiction within this judicial district with respect to this civil action; and/or (c) a substantial part of the events or omissions giving rise to the claim occurred within this judicial district. 28 U.S.C. § 1391.

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[5] Id.
[6] Id.

STATEMENT OF FACTS

AHF's Uniquely Successful Treatment of People of Limited Economic Means Living with HIV/AIDS

7. Once considered a death sentence, HIV/AIDS can now be treated with sophisticated medications in combination with other medical care and support services, but these medications must be taken daily according to strictly observed regimens for a patient's entire life. AHF's treatment of HIV/AIDS is uniquely successful because it involves an integrated, coordinated care model – developed, improved, and mastered over several decades treating and otherwise caring for people living with HIV/AIDS – focused on intensive, highly structured and rigidly scheduled drug regimens, including specialty anti-retroviral ("ARV") drugs, and interactions between patients and various AHF expert service providers – including physicians, case managers, social workers, and, of course, pharmacists – to ensure that AHF's patients receive all the information, care, and medications necessary to live full lives. AHF and its pharmacies treat "the whole patient" using this approach, which practically means that AHF pharmacy customers fill all kinds of prescriptions, not just ARV drugs. This carefully developed integrated care model saves lives otherwise lost. At bottom, AHF's treatment model results in far higher percentages of AHF's patients achieving viral suppression (such that the HIV virus is not detectable in the patient) than patients of other healthcare providers. 84% of AHF's patients/pharmacy customers achieve viral suppression compared to a national

average of 62%. AHF's treatment stops not only sickness; it stops transmission of the HIV virus. People who are virally suppressed are rendered virtually noninfectious – there is so little of the virus in the body, it is extremely difficult to transmit.

8. ARV drugs, mentioned above, are the active medications used to treat and control HIV. If a person living with HIV/AIDS stops taking prescribed ARV drugs, those drugs could lose effectiveness with the patient, and the failure to take ARV drugs regularly and precisely as prescribed can lead to a patient's death. Accordingly, AHF pharmacies have a sharp focus on ensuring patients take their medications when they are supposed to, i.e., adhere to their medication, in no small part because ARV drugs require proper adherence to control HIV/AIDS and to maintain the efficacy of those drugs for a patient. AHF's pharmacists consider ensuring adherence as among the core functions of their roles at AHF.

9. AHF's prescribing physicians are dedicated to serving people living with HIV/AIDS and are among the most experienced providers in the country. AHF physicians are accredited by the American Academy of HIV Medicine, and many AHF physicians have been treating patients since the earliest days of the HIV epidemic in the United States. AHF's physicians have unparalleled expertise treating patients living with HIV/AIDS and treat more HIV patients daily than any other provider group in the country. Moreover, several AHF physicians are also engaged in cutting edge clinical research devoted to finding better treatment for their HIV

patients.

10. AHF pharmacies hire only individuals who are knowledgeable about HIV/AIDS, are highly sensitive to the particular challenges of AHF's patient population and understand the complex drug interactions inherent with ARV medicines. AHF pharmacists must be certified by the American Academy of HIV Medicine. Moreover, all AHF pharmacies are accredited as specialty pharmacies by both the Accreditation Commission for Health Care and the Utilization Review Accreditation Commission. All AHF pharmacy services are provided by staff employed by AHF. AHF outsources none of its services, including after-hours calls (24/7), computer services, and clinical and dispensing services.

11. The pharmacies themselves are, in most instances, co-located with AHF's healthcare centers, so that pharmacists can better coordinate with the case management team and expert, primary care providers to ensure that patients timely receive their medication and remain compliant with their medication regimens and care plan. To improve adherence, AHF provides medications in customized, specialty-adherence packaging when appropriate, discreet packaging that prevents disclosures of the drugs being delivered, and further adherence counseling and education in line with the communications from the primary care provider.

Medicare Part D and CMS

12. This case concerns, among other things, Medicare Part D funds. Medicare is a federally funded health insurance program primarily for elderly and

disabled persons established under Title XVIII of the Social Security Act, 42 U.S.C. § 1395 *et seq*. Part D, at issue here, provides outpatient prescription drug coverage to Medicare beneficiaries – older adults and people with long-term disabilities – enrolled in private plans. See 42 U.S.C. §1395, et seq. (Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. 108-173, 117 Stat. 2066 (2003) ("Medicare Modernization Act")). As of June 2021, 48 million people with Medicare are currently enrolled in plans that provide the Medicare Part D drug benefit either in standalone Part D plans or in Medicare Advantage Part D ("MAPD"), representing more than three-quarters (77%) of all Medicare beneficiaries ("Beneficiaries").[7]

13. The Center for Medicare and Medicaid Services ("CMS") is the operating division within the United States Department of Health and Human Services ("HHS") responsible for administering, among other things, the Part D program. CMS promulgates rules and regulations governing Part D plans. A Part D plan is a contract an organization, like ESI's insurance company clients, enters into with CMS, pursuant to which the organization sponsors a Part D insurance plan for prescription drugs for Beneficiaries. ESI, in its capacity as a PBM, enters into contracts with its clients pursuant to which ESI manages the pharmacy benefits of

[7] Juliette Cubanski, "Key Facts About Medicare Part D Enrollment, Premiums, and Cost Sharing in 2021," https://www.kff.org/medicare/issue-brief/key-facts-about-medicare-part-d-enrollment-premiums-and-cost-sharing-in-2021/ (last accessed September 30, 2022).

its clients' subscribers.

14. ESI is, as defined by CMS, a "first tier downstream entity" which is required to comply with its insurance company clients' contracts – including the Medicaid Part D insurance plans – with CMS.[8] By virtue of its status as PBM that is a "first tier downstream entity," ESI is also bound by the regulations and laws, including Any Willing Provider laws, applicable to ESI's insurance company clients.[9]

15. CMS, however, does not involve itself in policing contracts between first tier entities and health care providers and, instead, leaves it to the parties to litigate or otherwise resolve such disputes. "However, whether a Part D sponsor has permitted a pharmacy an opportunity to participate in its network, or whether a

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[8] Medicare Managed Care Manual ("Medicare Manual"), Ch. 11 – Medicare Advantage Application Procedures and Contract Requirements, §§10 (Definitions of "downstream entity" and "first tier entity") and 100.4 (Provider and Supplier Contract Requirements), https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/mc86c11.pdf (last accessed September 30, 2022).

[9] 42 CFR §423.100 ("Each and every contract governing Part D sponsors and first tier downstream and related entities must contain a provision requiring that any services or activities performed by a first tier downstream and related entity, in accordance with the contract, are consistent and comply with a Plan D sponsors' contractual obligations"); Medicare Manual, Ch. 11 – Medicare Advantage Application Procedures and Contract Requirements, §100.4 (Provider and Supplier Contract Requirements), https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/mc86c11.pdf (last accessed September 30, 2022) "Contracts must contain accountability provisions specifying: That first tier and downstream entities must comply with Medicare laws, regulations, and CMS instructions (422.504(i)(4)(v)…".

pharmacy can meet or has met contract terms in compliance with the law and CMS' regulations at 42 CFR 423.120(a)(8)(i) are fact-specific questions that are generally best left between the parties."[10]

16. CMS also promulgates Star Ratings for the purpose of evaluating, ranking and publicizing the performance of Medicare Part D plans. CMS rates plans on a one-to-five scale, with a five rating representing the best performers. The best performing plans receive benefits, like the ability to advertise their high ratings and to enroll new members outside of enrollment periods. The best performing plans also stand to receive handsome monetary bonuses from CMS. The Star Ratings are based on a plan's performance with respect to numerous Star metrics, only a few of which – like adherence of Beneficiaries to taking certain medications – ESI "uses" in connection with most of its Claw Back Programs.

17. CMS did not intend for the Star Ratings, or performance with respect to the Star metrics, to be used to extract money from healthcare providers. In fact, CMS does not use the Star Ratings or the Star metrics to impose monetary penalties on plan sponsors. The only penalty associated with a low Star Rating for a plan sponsor is the low rating itself. Yet, as shown below, ESI perverts the Star metrics in the false name of "pharmacy performance" to create and grow a profit center using

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[10] Medicare Prescription Drug Benefit Manual, Chapter 5: Benefits and Beneficiary Protections, §50.8.1, https://www.cms.gov/regulations-and-guidance/guidance/manuals/downloads/mc86c05.pdf (last accessed September 30, 2022).

Part D funds for both ESI and its plan sponsor clients.

The Agreements Between AHF and ESI

18. In providing drugs to enrolled Beneficiaries, Part D plan sponsors regularly subcontract with PBMs. The United States Supreme Court recently described PBMs as follows:

> Pharmacy benefit managers (PBMs) are a little-known but important part of the process by which many Americans get their prescription drugs. Generally speaking, PBMs serve as intermediaries between prescription-drug plans and the pharmacies that beneficiaries use. When a beneficiary of a prescription-drug plan goes to a pharmacy to fill a prescription, the pharmacy checks with a PBM to determine that person's coverage and copayment information. After the beneficiary leaves with his or her prescription, the PBM reimburses the pharmacy for the prescription, less the amount of the beneficiary's copayment. The prescription-drug plan, in turn, reimburses the PBM.

Rutledge v. Pharm. Care Mgmt. Ass'n (2020) ___U.S.___ [141 S.Ct. 474, 478, 208 L.Ed.2d 327, 327].

19. AHF entered into agreements with ESI that permitted AHF's pharmacies to fill prescriptions for Part D Beneficiaries whose benefits ESI manages as a PBM. These agreements created exclusive and mandatory "networks" for ESI's plan sponsor clients. Beneficiaries must use these networks or pay high costs for out-

of-network services. AHF's pharmacies cannot dispense prescriptions to such Beneficiaries for reimbursement with Part D funds unless ESI agrees. With HIV drugs, out-of-network costs can be thousands of dollars, making it virtually impossible for Beneficiaries to elect out-of-network services. If AHF is excluded from ESI's networks, then AHF can no longer render its life saving services to network Beneficiaries, notwithstanding how long AHF served those Beneficiaries in the past.

20. At all times relevant hereto, ESI had and has today considerable bargaining leverage as one of the nation's largest PBMs. If AHF did not sign up to ESI's networks, AHF would lose the ability to provide services to its patients – the vast majority of whom are people of limited economic means living with HIV/AIDS – in those networks. As noted, those networks are exclusive, and there is no alternative if AHF wants to continue to serve the members of the Part D plans in ESI' networks.

21. The parties did not engage on a level playing field. ESI and its health plan partners set the terms. The growth in the range of the Claw Back and the raw amount of claw back dollars demonstrates the unequal bargaining power of the parties here and industry wide. ESI and its plan partners have no competitive check on how much they increased the claw back or in how they administered the Claw Back Programs, including in purporting to score the "performance" of pharmacies or in determining the amount of the claw back. There is no valid business reason for

the escalating percentages of all prescription reimbursements recouped by ESI, and this growth shows unchecked economic power. In addition, there is no valid business reason for applying the claw back to all prescriptions filled by AHF's pharmacies, even of very expensive ARV drugs, which are not measured in ESI's Claw Back Programs.

Claw Back Programs Generally

22. CMS initially permitted DIR as a means to track rebates and other price adjustments made by PBMs with the overall goal being that reimbursement to pharmacies take place at the lowest negotiated price, minimizing cost shifting to Part D Beneficiaries.[11] CMS intended DIR as a way to create transparency around the true costs of drugs. This, in turn, helps CMS determine how much it will pay Plan Sponsors for providing Part D benefits and helps Medicare Beneficiaries keep their cost-sharing down. Basically, CMS intended that DIR represent all the price concessions made to Part D sponsors that impact the ultimate cost of the drug.

23. Since 2016, however, DIR has morphed into the Claw Back Programs, which are used by PBMs, including ESI, to boost their profits without regard to the cost of Part D covered drugs borne by Beneficiaries or the taxpayer.[12] Essentially,

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[11] Michael Gabay, ""Direct and Indirect Remuneration Fees: The Controversy Continues," 52(11) HOSP. PHARM., 740, (Dec. 2017), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5735766/ (last accessed September 30, 2022).

[12] Id.

claw backs are payments or payment adjustments made by PBMs after the point-of-sale that alter the agreed cost of Part D covered drugs as between PBMs and pharmacies.

24. More specifically, Claw Back Programs involve PBMs taking back from pharmacies massive public Part D monies earmarked to pay for prescriptions for people of limited financial means and paying that money back to the Part D plan sponsors (insurers), resulting in Beneficiaries experience higher prescription costs, pharmacies like AHF receiving millions of dollars less than the negotiated reimbursement rates for those public Part D monies, and massive profits for PBMs and their private insurer clients. This is an industry wide phenomenon not unique to ESI. From 2016 to 2020, the industry-wide Claw Back grew from $2.125 billion to $9.535 billion.[13]

25. Most Claw Back Programs purport to use CMS's Star Ratings, mentioned above, to base the claw back on pharmacy "performance," but the Claw Back Programs pervert the Star Ratings, both in their application and purpose, do not actually "use" them, and do not fairly or accurately measure "performance." As discussed more fully below, PBMs set arbitrary, unachievable and unreasonable

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[13] "Medicare Program; Contract Year 2023 Policy and Technical Changes to the Medicare Advantage and Medicare Prescription Drug Benefit Programs"), 87 Fed. Reg. 27704, 27834, https://www.federalregister.gov/documents/2022/05/09/2022-09375/medicare-program-contract-year-2023-policy-and-technical-changes-to-the-medicare-advantage-and (last accessed September 30, 2022).

"one size fits all" "performance" metrics often relying on data from an aggregate of pharmacies, rather than the individual pharmacy subject to the "performance" scoring, to claw back millions of dollars.

Statutory and Regulatory Background – The Medicare Modernization Act Requires Plan Sponsors To Provide Enrollees With Access To "Negotiated Prices"

26. Plan sponsors and PBMs must make available to Beneficiaries the "negotiated prices" for covered Part D drugs, as that term is defined in the Medicare Modernization Act. The Medicare Modernization Act specifically requires plan sponsors to, among other things, "provide enrollees with access to negotiated prices used for payment for covered part D drugs." 42 U.S.C. § 1395w-102(d)(1)(A). The Act further requires that, "[f]or purposes of [part D], negotiated prices shall take into account negotiated price concessions, such as discounts, direct or indirect subsidies, rebates, and direct or indirect remunerations, for covered part D drugs, and include any dispensing fees for such drugs." 42 U.S.C. § 1395w-102(d)(1)(B) (emphasis added). In other words, plan sponsors were to give to Part D plan Beneficiaries the benefit of the prices the plan sponsors actually pay to pharmacies, net of any price reductions, like those price reductions forced upon AHF's pharmacies by the Claw Back Programs.

27. Congress intended that "negotiated price concessions" would include *all pharmacy price concessions*, without exception. See H.R. Rep. No. 108-391, at

438 (2003) (Conf. Rep.) ("Qualified drug plans would be required to provide beneficiaries with access to negotiated prices (including all discounts, direct or indirect subsidies, rebates, other price concessions, or direct or indirect remunerations), regardless of the fact that no benefits may be payable."); H.R. Rep. No. 108-178, pt. 1, at 184 (2003) (House Report) ("[A]ll PDP plans will be required to make available to their enrollees the benefit of all price discounts").

28. The Claw Back Programs grew and flourished as result of specific definitions of "negotiated prices" promulgated by CMS over the years, including most importantly a regulation effective January 1, 2016 (now no longer in effect, as described below), in which CMS stated an exception to the definition of negotiated prices that swallowed the rule and inaugurated the specific types of PBM abuses using the Claw Back Programs at issue in this case.

The 2005 and 2009 Definitions Of "Negotiated Prices"

29. Prior to January 1, 2016, HHS had promulgated regulatory definitions of "negotiated prices" that permitted plan sponsors to elect what DIR they would pass to Beneficiaries and what DIR would be rebated to the plan sponsors. 70 Fed. Reg. 4194, 4,534 (emphasis added); *see also* 42 C.F.R. § 423.100 (2005); 74 Fed. Reg. 1494, 1,544; 42 C.F.R. § 423.100 (2009). HHS explained in 2005 that it interpreted the governing statute as "requir[ing] that 'discounts, direct or indirect subsidies, rebates, other price concessions, and direct or indirect remunerations' be taken into account in establishing covered Part D drug negotiated prices." 70 Fed.

Reg. 4194, 4,245 (citation omitted).

The 2016 Definition Of "Negotiated Prices" – Rebates to Plan Sponsors Forbidden Except for Those That "Cannot Reasonably be Determined at Point of Sale"

30. Effective January 1, 2016, CMS amended its definition of "negotiated prices" in a fashion that *forbade the rebating to plan sponsors of any portion of the "negotiated prices" and removed the election for plan sponsors to determine what DIR to pass onto plan beneficiaries*, as follows:

> Negotiated prices means prices for covered Part D drugs that meet all of the following: (1) The Part D sponsor (or other intermediary contracting organization) and the network dispensing pharmacy or other network dispensing provider have negotiated as the amount such network entity will receive, in total, for a particular drug. (2) Are inclusive of all price concessions from network pharmacies except those contingent price concessions *that cannot reasonably be determined at the point-of-sale*; and (3) Include any dispensing fees; but (4) Excludes additional contingent amounts, such as incentive fees, if these amounts increase prices and cannot reasonably be determined at the point-of-sale. (5) *Must not be rebated back to the Part D sponsor (or other intermediary contracting organization) in full or in part.*

42 C.F.R. § 423.100 (emphasis added).

31. By requiring all pharmacy price concessions to be included in the negotiated price, which as noted above the Medicare Modernization Act requires plans to make available to Beneficiaries, CMS said that it sought to "ensure that negotiated prices have a consistent meaning, provide for increased transparency in cost reporting to CMS, and allow for meaningful price comparisons between Part D sponsors." 79 Fed. Reg. 29,844, 29,878 (May 23, 2014) (preamble to final rule). CMS further stated that "we are revising our proposed definition of negotiated price to allow a *narrow exception* to the requirement that all pharmacy price concession [sic] be included in the negotiated price for those contingent pharmacy price concessions that cannot reasonably be determined at the point-of-sale." 79 Fed. Reg. 29,844, 29,878 (emphasis added).

PBMs Develop the Claw Back Programs to Exploit the "Reasonably Determined" Exception

32. As noted above, ESI's Claw Back Programs at issue in this case exploited the "reasonably determined" exception so that ESI could funnel Part D funds into its own coffers and the coffers of its plan sponsor clients. PBMs latched onto the "reasonably determined" exception to "negotiated prices" and designed Claw Back Programs specifically geared to skirt CMS's prohibition on rebates back to plan sponsors. In the ensuing years, PBMs and their plan sponsor clients first doubled the Claw Back, from around $2.125 billion in 2016 to around $4 billion in

2017.[14] In 2018 the Claw Back was about $6.3 billion.[15] In 2019, the Claw Back rocketed to around $8.1 billion. In 2020, the Claw Back reached $9,535,197,775.[16] In 2015, before the "reasonably determined" exception went into effect, the Claw Back was about $1.7 billion.[17]

HHS/CMS Expresses Concerns and Questions About Claw Back Programs and Their Negative Impact on Beneficiaries

33. In 2017, in a "Request for Information," HHS acknowledged the error of its ways in creating the "reasonably determined" exception. HHS explained that, despite its intention that the "reasonably determined exception" would be narrow in scope, the "exception…applies more broadly than we had initially envisioned because of the shift by Part D sponsors and their PBMs towards these types of contingent pharmacy payment arrangements, and, as a result, this exception *prevents the current policy from having the intended effect on price transparency, consistency, and beneficiary costs*." 82 Fed. Reg. 56336, 56,426 (emphasis added). In 2018, HHS acknowledged that "[w]hen price concessions are applied to reduce

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[14] "Medicare Program; Contract Year 2023 Policy and Technical Changes to the Medicare Advantage and Medicare Prescription Drug Benefit Programs"), 87 Fed. Reg. 27704, 27834, https://www.federalregister.gov/documents/2022/05/09/2022-09375/medicare-program-contract-year-2023-policy-and-technical-changes-to-the-medicare-advantage-and (last accessed September 30, 2022).

[15] Id.

[16] Id.

[17] Id

the negotiated price at the point of sale, some of the concession amount is apportioned to reduce beneficiary cost-sharing," and "*when price concessions are applied after the point of sale,… the majority of the concession amount accrues to the plan, and the remainder accrues to the government*." 83 Fed. Reg. 62152, 62175 (emphasis added). In other words, PBMs and their clients used the Claw Back Programs and the "reasonably determined" exception to funnel massive funds into PBM and plan sponsor coffers.

34. Moreover, HHS acknowledged that the then-current regulatory scheme adversely affects Part D Beneficiaries who are most in need, forcing individuals who require the most pharmacy benefits to pay more for their medications. *See id*. at 62,174. It said that:

> When pharmacy price concessions are not reflected in the price of a drug at the point of sale, beneficiaries might see lower premiums, but they do not benefit through a reduction in the amount they must pay in cost-sharing, and thus, *end up paying a larger share of the actual cost of a drug*. Moreover, given the increase in pharmacy price concessions in recent years, when the point-of-sale price of a drug that a Part D sponsor reports . . . as the negotiated price does not include such discount, *the negotiated price is rendered less transparent at the individual prescription level and less representative of the actual cost of the drug for the sponsor*.

Id. (emphasis added); see also id. at 62,176 ("For many Part D beneficiaries who utilize drugs and thus incur cost-sharing expenses, this means, *on average, higher overall out-of-pocket costs*.") (Emphasis added).

CMS Begins to Scrutinize PBM Abuses with So-Called "Performance Measures" for Claw Back Programs

35. As PBMs and their clients clawed back millions, then hundreds of millions, then billions in public Part D funds using the Claw Back Programs, PBMs, including ESI, took great pains to cloud in secrecy their so-called "performance metrics" and their methods for calculating Claw Back Program scores. CMS initiated a new rule, effective for contract year 2022, requiring plan sponsors to disclose the actual performance measures used in their programs.[18] 42 C.F.R. §423.514.

36. CMS's reasons for requiring disclosure of Claw Back Program metrics included "…concerns from pharmacies that the measures plans use to assess their

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[18] 42 C.F.R. §423.514 (emphasis added), as effective for plan year 2020, reads in full as follows:

> (a) Required information. Each Part D plan sponsor must have an effective procedure to develop, compile, evaluate, and report to CMS, to its enrollees, and to the general public, at the times and in the manner that CMS requires, statistics indicating the following —
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> (1) The cost of its operations.
>
> (2) The patterns of utilization of its services.
>
> (3) The availability, accessibility, and acceptability of its services.
>
> (4) Information demonstrating that the Part D plan sponsor has a fiscally sound operation.
>
> (5) ***Pharmacy Performance Measures***;
>
> (6) Other matters that CMS may require.

performance are *unattainable or otherwise unfair*."[19] Because Claw Back Programs can impact pharmacy reimbursements and ultimately pharmacy accessibility for Part D plan Beneficiaries, CMS determined that it should better understand how the programs work.

> The measures used by plans potentially impact pharmacy reimbursements. Therefore, starting January 1, 2022, CMS is requiring Part D plans to disclose pharmacy performance measures to CMS, which will enable CMS to better understand how such measures are applied. CMS will also be able to report pharmacy performance measures publicly to increase transparency on the process and to inform the industry in its new efforts to develop a standard set of pharmacy performance measures.[20]

37. CMS noted several potential problems with Claw Back Programs, all of which exist in this case, and further explained as follows:

> Knowledge of the industry's pharmacy performance measures would also provide transparency to the process and likely confirm or dispel the idea that many of the measures may not provide appropriate metrics

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[19] Contract Year 2022 Medicare Advantage and Part D Final Rule (CMS-4190-F2) Fact Sheet, https://www.cms.gov/newsroom/fact-sheets/contract-year-2022-medicare-advantage-and-part-d-final-rule-cms-4190-f2-fact-sheet (last accessed September 30, 2022) (emphasis added).

[20] Id.

across all types of pharmacies. Once collected, we stated that CMS would publish the list of pharmacy performance measures reported to increase public transparency.[21]

CMS Eliminates "Claw Back Programs" Starting on January 1, 2024

38. On January 12, 2022, CMS proposed a rule change that would eliminate the "reasonably determined" exception, effective January 1, 2024 and would amend the definition of "negotiated price" at 42 C.F.R. § 423.100 to mean the lowest amount a pharmacy could receive as reimbursement for a covered Part D drug under its contract with the Part D sponsor or the sponsor's intermediary (that is, the amount the pharmacy would receive net of the maximum possible reduction that could result from any contingent pharmacy payment arrangement).

39. CMS stated that the emergence of Claw Back Programs led to "negotiated prices" frequently being higher than the final payment to pharmacies. Such higher negotiated prices led to higher Beneficiary cost-sharing and faster Beneficiary advancement through the Part D benefit. CMS also noted the explosive growth of the claw back such that the claw back accounts form a larger share than ever before of total DIR and a larger share of total gross drug costs in the Part D program. CMS further noted that Part D sponsors and their contracted PBMs have been increasingly successful in recent years in negotiating price concessions from

[21] 86 Fed. Reg. 5864, 5955.

network pharmacies. Such price concessions are negotiated between pharmacies and sponsors or their PBMs, independent of CMS, and are often tied to the pharmacy's performance on various measures defined by the sponsor or its PBM. CMS noted that performance-based pharmacy price concessions, net of all pharmacy incentive payments, increased, on average, nearly 170 percent per year between 2012 and 2020 and now comprise the second largest category of DIR received by sponsors and PBMs, behind only manufacturer rebates.

40. Ultimately, CMS observed that Claw Back Programs cause Beneficiaries who utilize drugs to pay a larger share of the actual cost of a drug. Moreover, when the point-of-sale price of a drug that a Part D sponsor reports to CMS as the negotiated price does not include such discounts, the negotiated price of each individual prescription is rendered less transparent and less representative of the actual cost of the drug for the sponsor.

41. CMS reiterated that the "reasonably determined" exception turned out to apply more broadly than it had initially envisioned because of the shift by Part D sponsors and their PBMs towards Claw Back Programs. Nearly all performance-based pharmacy payment adjustments may be excluded from the negotiated price on the grounds that they cannot reasonably be determined at the point-of-sale. CMS concluded that, as a result, the "reasonably determined" exception prevents the current policy from having the intended effect on price transparency, consistency (by reducing differential reporting of pharmacy payment adjustments by sponsors),

and Beneficiary cost. The proposed rule eliminating Claw Back Programs would, in CMS's view, achieve the goals of meaningful price transparency, consistent application of all pharmacy payment concessions by all Part D sponsors, and prevention of cost shifting to Beneficiaries and tax payers.

42. On April 29, 2022, CMS announced that it amended the definition of "negotiated price" and provided, for the first time, a definition of "price concession," to curb PBM and plan sponsor abuses using the Claw Back Programs.[22] In particular, CMS amended 42 C.F.R. §423.100 as follows to include in alphabetical order a definition of "price concession:"

> Price concession means any form of discount, direct or indirect subsidy, or rebate received by the Part D sponsor or its intermediary contracting organization from any source that serves to decrease the costs incurred under the Part D plan by the Part D sponsor. Examples of price concessions include but are not limited to: discounts, chargebacks, rebates, cash discounts, free goods contingent on a purchase agreement, coupons, free or reduced-price services, and goods in kind.

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[22] "Medicare Program; Contract Year 2023 Policy and Technical Changes to the Medicare Advantage and Medicare Prescription Drug Benefit Programs"), 87 Fed. Reg. 27704, 27899, https://www.federalregister.gov/documents/2022/05/09/2022-09375/medicare-program-contract-year-2023-policy-and-technical-changes-to-the-medicare-advantage-and (last accessed September 30, 2022).

42 C.F.R. §423.100[23]. CMS amended the definition of "negotiated price" such that the definition now reads as follows:

> Negotiated price means the price for a covered Part D drug that—
>
> (1) The Part D sponsor (or other intermediary contracting organization) and the network dispensing pharmacy or other network dispensing provider have negotiated as the lowest possible reimbursement such network entity will receive, in total, for a particular drug;
>
> (2) Meets all of the following:
>
> (i) Includes all price concessions (as defined in this section) from network pharmacies or other network providers;
>
> (ii) Includes any dispensing fees; and
>
> (iii) Excludes additional contingent amounts, such as incentive fees, if these amounts increase prices[24]….

43. Notably, CMS deleted the "reasonably determined" exception, such that PBMs or Part D sponsors may no longer rely on the "reasonably determined" exception to use Claw Back Programs to rebate the Claw Back – Part D public funds – to their Part D sponsor clients. No longer may PBMs charge the Claw Back as they

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[23] Id., 87 Fed. Reg.at 27899, https://www.federalregister.gov/documents/2022/05/09/2022-09375/medicare-program-contract-year-2023-policy-and-technical-changes-to-the-medicare-advantage-and (last accessed September 30, 2022).

[24] Id.

used to and pocket any portion of that Claw Back as "profit."

44. Accordingly, starting on January 1, 2024, PBMs, including ESI will be forbidden from operating Claw Back Programs based on the "reasonably determined" exception, irrespective of the makeup or methodology of such programs.

The Federal Trade Commission Probe of PBMs and Claw Back Programs

45. On June 7, 2022, the Federal Trade Commission announced a probe of the PBM industry which will require PBMs to provide "information and records regarding their business practices," and which is "…aimed at shedding light on several practices that have drawn scrutiny in recent years including: fees and claw backs charged to unaffiliated pharmacies; …complicated and opaque methods to determine pharmacy reimbursement; …the use of specialty drug lists and surrounding specialty drug policies; the impact of rebates and fees from drug manufacturers on formulary design and the costs of prescription drugs to payers and patients."[25]

ESI's Claw Back Programs From 2020 to 2022

46. As noted, ESI's Claw Back Programs are nothing more than a scheme

[25] "FTC Launches Inquiry Into Prescription Drug Middlemen Industry – Agency to Scrutinize the Impact of Vertically Integrated Pharmacy Benefit Managers on the Access and Affordability of Medicine, https://www.ftc.gov/news-events/news/press-releases/2022/06/ftc-launches-inquiry-prescription-drug-middlemen-industry (last accessed September 30, 2022).

for ESI to extract from AHF money ESI agreed to pay to AHF, to pay that money to its client Part D plan sponsors (e.g., insurance companies like Cigna), and to circumvent government regulations that require Part D plan sponsors to give the benefit of that money to consumers – Part D plan Beneficiaries. The Claw Back Programs have nothing to do with measuring or improving pharmacy performance or healthcare outcomes, however, and the true purpose of the programs is to make ESI and its Part D plan sponsor clients more profitable and to improve ESI's competitive position as a PBM.

47. With the Claw Back Programs, ESI unilaterally reduced the contractually mandated reimbursement rates ESI agreed to pay to AHF for filling prescriptions for the Beneficiaries of the Part D plans of ESI's plan sponsor clients and paid to itself and its plan sponsor clients the vast majority of the monies clawed back by ESI using the Claw Back Programs. ESI used the Claw Back Programs to obfuscate the true cost of covered drugs to Beneficiaries instead of structuring the Claw Back Programs to improve or even measure pharmacy performance, neither of which the Claw Back Programs do, as discussed more fully below.

48. Although ESI styled its Claw Back Programs as a "performance program," the Claw Back Programs have never had anything to do with pharmacy performance and does not, and in fact cannot, properly measure pharmacy performance.

49. ESI does not calculate the Claw Back based on the performance of

AHF's pharmacies. In fact, the Claw Back Programs attribute to AHF's pharmacies the average Claw Back Program performance of other, unidentified pharmacies and then punishes AHF for such average performance by other pharmacies.

50. Also, the Claw Back Programs rely on so-called performance metrics not subject to any control by AHF's, or any other, pharmacies and, therefore, not indicative of pharmacy "performance." The performance metrics were not designed by CMS, and are not used by ESI, to measure or improve pharmacy performance. ESI crassly designed the Claw Back Programs to appear to mimic performance measures promulgated by CMS, the Star measures, but ESI misapplies and departs from those measures in numerous ways to calculate and extract monetary penalties, something never contemplated by CMS in developing the measures (which results in, among other things, AHF's pharmacies receiving less than the contractually mandated reimbursements).

51. ESI structured the Claw Back Programs such that the penalties assessed for "performance" become known to pharmacies only long after prescription filling events, such that performance problems cannot be timely addressed even if the performance metrics were within AHF's control.

52. Ultimately, there are numerous severe and intractable problems with the Claw Back Programs which reveal their true purposes:

- Most of the Claw Back Programs' performance measures appear to mimic CMS's Star measures, but ESI misapplies those

measures and uses them for a purpose for which they were never intended: to extract penalties from pharmacies that *de facto* reduce the contractually-agreed reimbursement rates, to keep those extracted funds from ESI's Part D plan sponsor clients' Beneficiaries, and to funnel those funds into its own and its Part D plan sponsor clients' coffers, all to better ESI's competitive position as a PBM.

- The adherence and dispensing based so-called "performance measures" for the Claw Back Programs (which are generally dispensing measures) punish AHF's pharmacies for the prescribing decisions made by prescribing healthcare professionals, for it is those professionals (and not pharmacists) who choose what to prescribe or not to prescribe in their professional judgment, and pharmacies cannot instruct prescribing professionals what to prescribe.
- Specifically, the Claw Back Programs punish AHF's pharmacies for decisions made by physicians and other prescribing professionals (and not pharmacists) *not to prescribe* drugs, like statins, that are in many instances contraindicated for people living with HIV/AIDS and could endanger their lives.
- The generic drug dispensing "performance measure" for the

Claw Back Programs has nothing whatsoever to do with pharmacy performance, is geared to reducing the plan sponsors' spending on drugs, again imposes penalties based on prescription decisions not made by pharmacists, and discriminates against specialty pharmacies like AHF, which prescribes a large proportion of drugs not available in generic, non-brand forms.

- There is a minimum penalty for the Claw Back Programs, which all pharmacies must pay even with perfect so-called "performance" scores.
- In scoring AHF's high-performing pharmacies, ESI imputes to AHF the average performance of other, unidentified pharmacies when AHF's pharmacies have no data to score, and ESI does not share with AHF's pharmacies the data on which the imputed means are calculated; the Claw Back Program, therefore, expressly does not score AHF's pharmacies based on their performance.
- The Claw Back itself is calculated on "ingredient cost" for all prescriptions filled, not just for those drugs measured by the Claw Back Programs. This means that, for specialty pharmacies like AHF's, which tend to prescribe on average more expensive, specialty drugs in significant volume than non-specialty

pharmacies, the claw back will almost always be higher for AHF's pharmacies than for other pharmacies, even poorly performing pharmacies.

- The Claw Back Programs are scored in such a fashion that pharmacies with smaller patient volumes are disproportionately impacted by isolated, aberrant instances of "poor" performance with respect to only one or two patients (if an AHF pharmacy has three patients who should be taking statins according to the Claw Back Programs' measures, and a prescribing healthcare professional does not prescribe statins to one of those patients, that AHF pharmacy score for the statin measure is 66%).
- The Claw Back Programs' scoring trimesters are cumulative, meaning that aberrant low scores from a single trimester could negatively impact a pharmacy's scores for any subsequent trimesters, thereby punishing pharmacies twice and even three times for the same "poor" performance.
- The Claw Back Programs are structured so that AHF's pharmacies are scored, and the Claw Back is taken from AHF's pharmacies, long after the scored prescription-filling events; there is no way for AHF's pharmacies to take any actions to improve their scores before those scores are generated and the

Claw Back is taken.

- By dangling the unachievable prospect of "better scores" and even performance incentive payments in front of AHF's pharmacies, ESI appears to expect AHF's pharmacies to perform some unspecified quality-related activities to try to improve their "performance," which presumably require the devoting of resources by AHF's pharmacies. Yet, as shown above, AHF's pharmacies have no control over the prescribing decisions of professionals permitted by law to write prescriptions (which pharmacists may not do). Instead of compensating AHF's pharmacies for its efforts by giving better scores or paying any meaningful performance incentives, ESI eats into the cost of all drugs dispensed by AHF's pharmacies whether they are measured by the Claw Back Programs or not.

53. Between 2020 and 2021, ESI clawed back from AHF the total amount of $3,174,542.01. Thus far in 2022, ESI has clawed back from AHF the total amount of $1,626,503.83.

54. ESI has used the Claw Back Programs to recoup unlawfully payments from AHF pharmacies located in California, Florida, Georgia, Illinois, Louisiana, Maryland, Mississippi, Nevada, New York, Ohio, Pennsylvania, South Carolina, Texas, Washington, the District of Columbia and Puerto Rico. AHF, therefore, seeks

damages, restitution and injunctive relief as redress for, among other things, ESI's repeated breaches of contract and the implied covenant of good faith and fair dealing, the adhesive and unconscionable nature of the terms of the Claw Back Programs, ESI's unfair business practices, and its violations of state and federal "Any-Willing-Provider" laws.

ESI's Underpayment of Guaranteed Effective Reimbursement Rates

55. The relevant contracts between the parties require that ESI pay to AHF guaranteed annual effective rates for each year. In 2019 (contract year ending 10/19/2020), ESI paid to AHF 1.46% less than the contract required, translating to an underpayment by ESI to AHF of $1,495,466. In 2020 (contract year ended 10/19/2021), ESI paid to AHF 3.06% less than the contract required, translating to an underpayment by ESI to AHF of $4,407,633 for that year.

COUNTS

FIRST COUNT

BREACH OF CONTRACT

56. AHF incorporates herein as if set forth fully all the preceding allegations of the Complaint.

57. AHF agreed to provide prescription drug services to patients who are Beneficiaries of Part D plans sponsored by ESI's clients and administered by ESI and with the full expectation that ESI would adhere to the terms of the applicable agreement and state and federal laws and regulations. Pursuant to the agreement, ESI

is obligated, among other things, to reimburse AHF in a timely fashion and according to a determinable formula for drugs dispensed to Part D Beneficiaries whose prescription benefits ESI administers. The agreements do not permit AHF to hide from AHF the true, net amounts ESI reimburses to AHF for drugs AHF dispenses. Nor do the agreements permit ESI to reimburse smaller, specialty pharmacies treating high-risk patients less money than reimbursed to other independent non-specialty pharmacies or pharmacies in very large pharmacy chains.

58. AHF fully performed all its obligations under the agreement, including dispensing medications to eligible patients and timely submitting claims for reimbursement in compliance with ESI's requirements.

59. ESI breached the agreements by, among other things, initiating the Claw Back Programs pursuant to which ESI, among other things, paid to AHF reimbursement rates lower than the rates to which ESI and AHF agreed.

60. ESI breached the agreements by, among other things, failing to reimburse AHF in amounts ESI agreed to reimburse AHF.

61. ESI's many breaches of the agreements include but are not limited to the following:

- The design and imposition on AHF, on a take it or leave it basis and with no negotiation, of Claw Back Programs under the false guise of measuring and rewarding pharmacy "performance", resulting in AHF's

pharmacies receiving smaller reimbursements for dispensing drugs than agreed by the parties.

- The design and imposition on AHF, on a take it or leave it basis and with no negotiation, of Claw Back Programs that do not measure pharmacy "performance" and are rigged to require massive claw backs no matter what pharmacies do.
- The design and imposition on AHF, on a take it or leave it basis and with no negotiation, of Claw Back Programs that purportedly rely on patient adherence to medication regimens but actually measure something with which pharmacies have nothing to do and cannot control: the writing of prescriptions by medical professionals other than pharmacists (who may not write prescriptions or control the good faith decisions by prescribing healthcare professionals).
- The design and imposition on AHF, on a take it or leave it basis and with no negotiation, of Claw Back Programs that take the Claw Back long after dispensing events such that pharmacy performance cannot be improved, even assuming that the Claw Back Programs actually measure pharmacy performance, which they do not.
- The design and imposition on AHF, on a take it or leave it basis and with no negotiation, of Claw Back Programs containing a "performance measure" based on the generic status of dispensed drugs which impose

penalties, again, based on prescription decisions not made by pharmacists, and discriminate against specialty pharmacies like AHF's, which prescribe a large proportion of drugs – including ARV drugs crucial to the treatment of people living with HIV/AIDS, not available in generic, non-brand forms.

- The design and imposition on AHF, on a take it or leave it basis and with no negotiation, of Claw Back Programs containing a minimum penalty all pharmacies must pay, even with perfect so-called "performance" scores.
- The design and imposition on AHF, on a take it or leave it basis and with no negotiation, of Claw Back Programs which, in the scoring process, impute to AHF's high-performing pharmacies the average performance of other, unidentified pharmacies when AHF's pharmacies have no data to score.
- The design and imposition on AHF, on a take it or leave it basis and with no negotiation, of Claw Back Programs for which the Claw Back itself is calculated on "ingredient cost" for all prescriptions filled, not just for those drugs measured by the Claw Back Programs.
- The design and imposition on AHF, on a take it or leave it basis and with no negotiation, of Claw Back Programs scored in such a fashion that pharmacies with smaller patient volumes are disproportionately

impacted by isolated, aberrant instances of "poor" performance with respect to only one or two patients (if an AHF pharmacy has three patients who should be taking statins according to the Claw Back Program's measures, and a prescribing healthcare professional does not prescribe statins to one of those patients, that AHF pharmacy score for the statin measure is 66%).

- The design and imposition on AHF, on a take it or leave it basis and with no negotiation, of Claw Back Programs for which the scoring trimesters are cumulative, meaning that aberrant low scores from a single trimester could negatively impact a pharmacy's scores for any subsequent trimesters, thereby punishing pharmacies twice and even three times for the same "poor" performance.

62. ESI's repeated breaches of the agreements in connection with the Claw Back Programs caused harm to AHF in an amount in excess of $10.7 million, to be proved at trial.

63. AHF is entitled to preliminary and permanent injunctive relief, forbidding and enjoining ESI from attempting to enforce the portions of the Claw Back Programs which constitute breaches of the agreements between the parties.

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SECOND COUNT

BREACH OF THE IMPLIED COVENANT OF

GOOD FAITH AND FAIR DEALING

64. AHF incorporates herein as if set forth fully all the preceding allegations of the Complaint.

65. Missouri law implies in every agreement, including the agreement at issue here, a covenant of good faith and fair dealing which can be breached even where the express terms are not violated. The implied covenant of good faith and fair dealing prohibits a party from doing anything to prevent the other contracting parties from receiving the benefits of the agreement.

66. AHF agreed to provide prescription drug services to patients in health plans administered by ESI in good faith and with the full expectation that ESI would adhere to the terms of the applicable agreement and applicable law and regulations. Pursuant to the applicable agreement, ESI is obligated to reimburse AHF in a timely fashion and according to a determinable formula for drugs dispensed to patients whose prescription benefits ESI administers. The agreement does not permit ESI to hide from AHF the true, net amounts ESI reimburses to AHF for drugs AHF dispenses.

67. AHF fully performed all its obligations under the agreement, including dispensing medications to eligible patients and timely submitting claims for reimbursement in compliance with ESI's requirements.

68. ESI acted in bad faith and breached the implied covenant of good faith and fair dealing in the unilateral imposition, without negotiation and on a take it or leave it basis, and operation of the Claw Back Programs without regard to improving the quality of patient care. The Claw Back Programs have nothing to do with enhancing or improving the "performance" of pharmacies in the context of patient care. As administered, the Claw Back Programs permit ESI to penalize AHF's pharmacies for acts and decisions not subject to their control. The Claw Back Programs also permit ESI to penalize AHF for medical decisions taken by expert treating physicians and, in certain circumstances, seek to force decisions harmful to the health of people living with HIV/AIDS. Ultimately, the Claw Back Programs result in AHF's pharmacies receiving lower reimbursements for dispensing drugs to Part D Beneficiaries than the parties had bargained for, with the vast majority of the claw back flowing back into the coffers of Part D plan sponsors as profit.

69. ESI's many breaches of the implied covenant of good faith and fair dealing include but are not limited to the following:

- The design and imposition on AHF, on a take it or leave it basis and with no negotiation, of Claw Back Programs under the false guise of measuring and rewarding pharmacy "performance" resulting in AHF's pharmacies receiving smaller reimbursements for dispensing drugs than agreed by the parties.

- The design and imposition on AHF, on a take it or leave it basis and with no negotiation, of Claw Back Programs that do not measure pharmacy "performance" and are rigged to require massive claw backs no matter what pharmacies do.
- The design and imposition on AHF, on a take it or leave it basis and with no negotiation, of Claw Back Programs that purportedly rely on patient adherence to medication regimens but actually measure something with which pharmacies have nothing to do and cannot control: the writing of prescriptions by medical professionals other than pharmacists (who may not write prescriptions or control the good faith decisions by prescribing healthcare professionals).
- The design and imposition on AHF, on a take it or leave it basis and with no negotiation, of Claw Back Programs that take the Claw Back long after dispensing events such that pharmacy performance cannot be improved, even assuming that the Claw Back Programs actually measure pharmacy performance, which they do not.
- The design and imposition on AHF, on a take it or leave it basis and with no negotiation, of Claw Back Programs containing a "performance measure" based on the generic status of dispensed drugs which impose penalties, again, based on prescription decisions not made by pharmacists, and discriminate against

specialty pharmacies like AHF's, which prescribe a large proportion of drugs – including ARV drugs crucial to the treatment of people living with HIV/AIDS, not available in generic, non-brand forms.

- The design and imposition on AHF, on a take it or leave it basis and with no negotiation, of Claw Back Programs containing a minimum penalty all pharmacies must pay, even with perfect so-called "performance" scores.
- The design and imposition on AHF, on a take it or leave it basis and with no negotiation, of Claw Back Programs which, in the scoring process, impute to AHF's high-performing pharmacies the average performance of other, unidentified pharmacies when AHF's pharmacies have no data to score.
- The design and imposition on AHF, on a take it or leave it basis and with no negotiation, of Claw Back Programs for which the Claw Back itself is calculated on "ingredient cost" for all prescriptions filled, not just for those drugs measured by the Claw Back Programs.
- The design and imposition on AHF, on a take it or leave it basis and with no negotiation, of Claw Back Programs scored in such a fashion that pharmacies with smaller patient volumes are disproportionately impacted by isolated, aberrant instances of "poor" performance with respect to only one or two patients (if an

AHF pharmacy has three patients who should be taking statins according to the Claw Back Programs' measures, and a prescribing healthcare professional does not prescribe statins to one of those patients, that AHF pharmacy score for the statin measure is 66%).

- The design and imposition on AHF, on a take it or leave it basis and with no negotiation, of Claw Back Programs for which the scoring trimesters are cumulative, meaning that aberrant low scores from a single trimester could negatively impact a pharmacy's scores for any subsequent trimesters, thereby punishing pharmacies twice and even three times for the same "poor" performance.

70. ESI has used the Claw Back Programs to its own pecuniary benefit and to the pecuniary benefit of its plan sponsor clients to deprive AHF of the benefit of its bargain and to better ESI's competitive position as a PBM.

71. ESI's repeated breaches of the implied covenant in connection with the Claw Back Programs caused harm to AHF in an amount in excess of $10.7 million, to be proved at trial.

72. AHF is entitled to preliminary and permanent injunctive relief, forbidding and enjoining ESI from attempting to enforce the portions of the Claw Back Programs which constitute breaches of the implied covenant of good faith and fair dealing.

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THIRD COUNT

UNENFORCEABLE UNCONSCIONABLE CONTRACTS

73. AHF incorporates herein as if set forth fully all the preceding allegations of the Complaint.

74. The terms of the Claw Back Programs, including but not limited to those set forth below, are both substantively and procedurally unconscionable and are, therefore, unenforceable:

- The design and imposition on AHF, on a take it or leave it basis and with no negotiation, of Claw Back Programs under the false guise of measuring and rewarding pharmacy "performance" resulting in AHF's pharmacies receiving smaller reimbursements for dispensing drugs than agreed by the parties.
- The design and imposition on AHF, on a take it or leave it basis and with no negotiation, of Claw Back Programs that do not measure pharmacy "performance" and are rigged to require massive claw backs no matter what pharmacies do.
- The design and imposition on AHF, on a take it or leave it basis and with no negotiation, of Claw Back Programs that purportedly rely on patient adherence to medication regimens but actually measure something with which pharmacies have nothing to do and cannot control: the writing of prescriptions by medical

professionals other than pharmacists (who may not write prescriptions or control the good faith decisions by prescribing healthcare professionals).

- The design and imposition on AHF, on a take it or leave it basis and with no negotiation, of Claw Back Programs that take the Claw Back long after dispensing events such that pharmacy performance cannot be improved, even assuming that the Claw Back Programs actually measure pharmacy performance, which they do not.
- The design and imposition on AHF, on a take it or leave it basis and with no negotiation, of Claw Back Programs containing a "performance measure" based on the generic status of dispensed drugs which impose penalties, again, based on prescription decisions not made by pharmacists, and discriminate against specialty pharmacies like AHF's, which prescribe a large proportion of drugs – including ARV drugs crucial to the treatment of people living with HIV/AIDS, not available in generic, non-brand forms.
- The design and imposition on AHF, on a take it or leave it basis and with no negotiation, of Claw Back Programs containing a

minimum penalty all pharmacies must pay, even with perfect so-called "performance" scores.

- The design and imposition on AHF, on a take it or leave it basis and with no negotiation, of Claw Back Programs which, in the scoring process, impute to AHF's high-performing pharmacies the average performance of other, unidentified pharmacies when AHF's pharmacies have no data to score.
- The design and imposition on AHF, on a take it or leave it basis and with no negotiation, of Claw Back Programs for which the Claw Back itself is calculated on "ingredient cost" for all prescriptions filled, not just for those drugs measured by the Claw Back Programs.
- The design and imposition on AHF, on a take it or leave it basis and with no negotiation, of Claw Back Programs scored in such a fashion that pharmacies with smaller patient volumes are disproportionately impacted by isolated, aberrant instances of "poor" performance with respect to only one or two patients (if an AHF pharmacy has three patients who should be taking statins according to the Claw Back Programs' measures, and a prescribing healthcare professional does not prescribe statins to one of those patients, that AHF pharmacy score for the statin measure is 66%).

- The design and imposition on AHF, on a take it or leave it basis and with no negotiation, of Claw Back Programs for which the scoring trimesters are cumulative, meaning that aberrant low scores from a single trimester could negatively impact a pharmacy's scores for any subsequent trimesters, thereby punishing pharmacies twice and even three times for the same "poor" performance.

75. AHF has suffered damages as a result of the unenforceable adhesive terms of the agreements pertaining to the Claw Back Programs in an amount in excess of $3.9 million, to be proved at trial.

76. AHF is entitled to preliminary and permanent injunctive relief, forbidding and enjoining ESI from attempting to enforce the portions of the agreement pertaining to the Claw Back Programs which are substantively and/or procedurally unconscionable.

77. ESI's unconscionable contract provisions caused harm to AHF in an amount in excess of $4.8 million, to be proved at trial.

78. AHF is entitled to preliminary and permanent injunctive relief, forbidding and enjoining ESI from attempting to enforce the unconscionable provisions that pertain to the Claw Back Programs.

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FOURTH COUNT

UNFAIR BUSINESS PRACTICES

CAL. BUS. & PROF. CODE, § 17200, ET. SEQ.

79. AHF incorporates herein as if set forth fully all the preceding allegations of the Complaint.

80. Section 17200 of the California Business and Professions Code provides that unfair competition includes any unlawful, unfair or fraudulent business act or practice.

81. Section 17200, et seq. "borrows" violations of other laws and treats these violations, when committed pursuant to business activity, as unlawful practices independently actionable and subject to the distinct remedies provided under of Section 17200 et seq.

82. The remedies and penalties under Section 17200 are cumulative to those imposed under the other laws.

83. As discussed above and shown further below, with respect to the Claw Back Programs, ESI engaged in, among others, the following unlawful, unfair and fraudulent business practices in violation of federal and state laws and applicable regulations also set forth below:

- The design and imposition on AHF, on a take it or leave it basis and with no negotiation, of Claw Back Programs under the false guise of measuring and rewarding pharmacy "performance"

resulting in AHF's pharmacies receiving smaller reimbursements for dispensing drugs than agreed by the parties.

- The design and imposition on AHF, on a take it or leave it basis and with no negotiation, of Claw Back Programs that do not measure pharmacy "performance" and are rigged to require massive claw backs no matter what pharmacies do.
- The design and imposition on AHF, on a take it or leave it basis and with no negotiation, of Claw Back Programs that purportedly rely on patient adherence to medication regimens but actually measure something with which pharmacies have nothing to do and cannot control: the writing of prescriptions by medical professionals other than pharmacists (who may not write prescriptions or control the good faith decisions by prescribing healthcare professionals).
- The design and imposition on AHF, on a take it or leave it basis and with no negotiation, of Claw Back Programs that take the Claw Back long after dispensing events such that pharmacy performance cannot be improved, even assuming that the Claw Back Programs actually measure pharmacy performance, which they do not.

- The design and imposition on AHF, on a take it or leave it basis and with no negotiation, of Claw Back Programs containing a "performance measure" based on the generic status of dispensed drugs which impose penalties, again, based on prescription decisions not made by pharmacists, and discriminate against specialty pharmacies like AHF's, which prescribe a large proportion of drugs – including ARV drugs crucial to the treatment of people living with HIV/AIDS, not available in generic, non-brand forms.
- The design and imposition on AHF, on a take it or leave it basis and with no negotiation, of Claw Back Programs containing a minimum penalty all pharmacies must pay, even with perfect so-called "performance" scores.
- The design and imposition on AHF, on a take it or leave it basis and with no negotiation, of Claw Back Programs which, in the scoring process, impute to AHF's high-performing pharmacies the average performance of other, unidentified pharmacies when AHF's pharmacies have no data to score.
- The design and imposition on AHF, on a take it or leave it basis and with no negotiation, of Claw Back Programs for which the Claw Back itself is calculated on "ingredient cost" for all

prescriptions filled, not just for those drugs measured by the Claw Back Programs.

- The design and imposition on AHF, on a take it or leave it basis and with no negotiation, of Claw Back Programs scored in such a fashion that pharmacies with smaller patient volumes are disproportionately impacted by isolated, aberrant instances of "poor" performance with respect to only one or two patients (if an AHF pharmacy has three patients who should be taking statins according to the Claw Back Programs' measures, and a prescribing healthcare professional does not prescribe statins to one of those patients, that AHF pharmacy score for the statin measure is 66%).
- The design and imposition on AHF, on a take it or leave it basis and with no negotiation, of Claw Back Programs for which the scoring trimesters are cumulative, meaning that aberrant low scores from a single trimester could negatively impact a pharmacy's scores for any subsequent trimesters, thereby punishing pharmacies twice and even three times for the same "poor" performance.

84. The above described conduct, acts, and omissions violated the state and federal laws and applicable regulations, set forth below.

85. Federal Medicare law, 42 C.F.R. § 423.505(b)(18), requires that all Part D plan sponsors, and their PBM intermediaries, agree to offer participating pharmacies a contract with "reasonable and relevant terms and conditions of participation." Such requirements have been uniformly and repeatedly emphasized by CMS.

86. ESI secretly employs and manipulates the Claw Back Programs to reduce greatly without rational, performance-related justification the reimbursements paid to AHF and to make providing services to ESI's members financially precarious for AHF. There is nothing reasonable about the Claw Back Programs or ESI's administration of them, and they have no relevance to pharmacy "performance." As a result of the drastically reduced reimbursement that flows from the Claw Back Programs, AHF is not able to provide the depth of services to treat its patients and is dissuaded from providing services at all.

87. ESI's above described actions and omissions violate 42 C.F.R. § 435.505(b)(18). AHF has suffered damages as a result of ESI's violations of 42 C.F.R. § 435.505(b)(18) in an amount in excess of $5 million, to be proved at trial. AHF is entitled to preliminary and permanent injunctive relief, forbidding and enjoining ESI from violating 42 C.F.R. § 435.505(b)(18).

88. Florida's Deceptive and Unfair Trade Practices Act, Fla. Stat. §§ 501.201-213 ("FDUTPA") protects the consuming public and legitimate business enterprises from unfair methods of competition, or unconscionable, deceptive, or

unfair acts or practices in the conduct of any trade or commerce. The FDUTPA declares unlawful all unfair methods of competition, unconscionable acts or practices, and unfair or deceptive acts or practices in the conduct of any trade or commerce. The FDUTPA defines a violation of the FDUTPA as violation of any law, statute, rule, regulation, or ordinance which proscribes unfair methods of competition, or unfair, deceptive, or unconscionable acts or practices.

89. AHF has suffered damages as result of ESI's violations of the FDUTPA in an amount in excess of the minimum jurisdictional amount of this Court, to be proved at trial. AHF is entitled to preliminary and permanent injunctive relief, forbidding and enjoining ESI from violating the FDUTPA.

90. New York General Business Law §349 prohibits any business or person from engaging in deceptive business practices in the conduct of any business, trade or commerce or in the furnishing of any service in New York State.

91. ESI's above-described actions and omissions violate New York General Business Law §349. AHF has suffered damages as a result of ESI's violations of New York General Business Law §349 in an amount in excess of the minimum jurisdictional amount of this Court, to be proved at trial. AHF is entitled to preliminary and permanent injunctive relief, forbidding and enjoining ESI from violating New York General Business Law §349.

92. Washington State's Consumer Protection Act, A.R.C.W §19.86, et seq., declares unfair methods of competition and unfair or deceptive acts or practices in

the conduct of any trade or commerce as unlawful. Any person injured in his or her business property by a violation of the Consumer Protection Act may bring a civil action to enjoin further violations, to recover actual damages, or both, together with costs of suit, including reasonable attorneys' fees.

93. ESI's above-described actions and omissions violate A.R.C.W §19.86, et seq. AHF has suffered damages as a result of ESI's violations of A.R.C.W §19.86, et seq., in an amount in excess of the minimum jurisdictional amount of this Court, to be proved at trial. AHF is entitled to preliminary and permanent injunctive relief, forbidding and enjoining ESI from violating A.R.C.W §19.86, et seq.

94. Georgia law, O.C.G.A. § 33-20-16, requires that every health care provider, including pharmacies, has the right to become a participating provider under such terms or conditions offered to other approved health care providers under similar circumstances.

95. The Illinois Managed Care Reform and Patient Rights Act, 215 CS 134/72(A), states that plans may not refuse to contract with pharmacy providers that can meet the plan's contractual terms. The terms and conditions in an agreement between health care plans and pharmacy providers "shall not discriminate against a pharmacy provider."

96. ESI's above-described actions and omissions violate 215 CS 134/72(A). AHF has suffered damages as a result of ESI's violations of 215 CS 134/72(A) in an amount in excess of the minimum jurisdictional amount of this

Court, to be proved at trial. AHF is entitled to preliminary and permanent injunctive relief, forbidding and enjoining ESI from violating 215 CS 134/72(A).

97. The Mississippi Code, Miss. Code Ann. § 83-9-6, requires plans to allow participants their choice of pharmacies that have agreed to participate in plans according to the terms offered by the insurer. Also, a plan may not deny such pharmacies the right to participate as a contract provider. A plan may not impose a monetary advantage or penalty under a health benefit plan that would affect a participant's choice among those pharmacies that have agreed to participate in the plan according to the terms offered by the insurer. Monetary advantages or penalties are defined as including higher copayments, reductions in reimbursement for services, or promotion of one participating pharmacy over another by these methods.

98. ESI's above-described actions and omissions violate Miss. Code Ann. § 83-9-6. AHF has suffered damages as a result of ESI's violations of Miss. Code Ann. § 83-9-6 in an amount in excess of the minimum jurisdictional amount of this Court, to be proved at trial. AHF is entitled to preliminary and permanent injunctive relief, forbidding and enjoining ESI from violating Miss. Code Ann. § 83-9-6.

PRAYER FOR RELIEF

Wherefore, AHF prays for relief as follows:

1. On the First Claim for Breach of Contract:

a. For general damages, according to proof at trial, in excess of the minimum jurisdictional amount of this Court; and

b. For pre-judgment and post-judgment interest at the applicable legal rate(s); and

c. For preliminary and permanent injunctions prohibiting ESI from demanding payment from AHF as a result of the operation of the Claw Back Programs and from breaching the agreement in the manners proved at trial; and

d. For expenses and costs of suit, including reasonable attorneys' fees, if allowable; and

2. On the Second Claim for Breach of the Implied Covenant of Good Faith and Fair Dealing:

a. For general damages, according to proof at trial, in excess of the minimum jurisdictional amount of this Court; and

b. For pre-judgment and post-judgment interest at the applicable legal rate(s); and

c. For preliminary and permanent injunctions prohibiting ESI from demanding payment from AHF as a result of the operation of the Claw Back Programs and from breaching the implied covenant of good faith and fair dealing in the manners proved at trial; and

d. For expenses and costs of suit, including reasonable attorneys' fees, if allowable; and

3. On the Third Claim for Unconscionable, Unenforceable Contract:

a. For general damages, according to proof at trial, in excess of the minimum jurisdictional amount of this Court; and

b. For pre-judgment and post-judgment interest at the applicable legal rate(s); and

c. For preliminary and permanent injunctions prohibiting the enforcement of the unconscionable, unenforceable contracts; and

d. For expenses and costs of suit, including reasonable attorneys' fees, if allowable; and

4. On the Fourth Claim for Unfair Business Practices Pursuant to California Business & Professions Code § 17200, et seq.:

a. For restitution, according to proof at trial, in excess of the minimum jurisdictional amount of this Court; and

b. For pre-judgment and post-judgment interest at the applicable legal rate(s); and

c. For preliminary and permanent injunctions prohibiting the violation of 42 C.F.R. § 423.505(b)(81); and

d. For expenses and costs of suit, including reasonable attorneys' fees, if allowable; and

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5. For all causes of action, for other and further relief that the Court deems just and proper.

Date: October 3, 2022

By: _____

AIDS HEALTHCARE FOUNDATION
Kirra N. Jones, SBN 60161 (MO)
Kirra.jones@ahf.org
6255 W. Sunset Blvd., 21st floor
Los Angeles, CA 90028
Tel: 323-860-5200

KIM RILEY LAW
Andrew F. Kim, SBN 156533 (CA)
akim@kimrileylaw.com
Pro Hac Vice application to be filed
Rebecca J. Riley, SBN 139085 (CA)
rriley@kimrileylaw.com
Pro Hac Vice application to be filed
9018 Balboa Boulevard, #552
Northridge, CA 91325
Tel: 818 216-5288
Tel: 323-547-8992

Attorneys for Plaintiff
AIDS HEALTHCARE FOUNDATION

DEMAND FOR JURY TRIAL

AHF demands a trial by jury of all causes of action so triable.

Date: October 3, 2022

By: _____

AIDS HEALTHCARE FOUNDATION
Kirra N. Jones, SBN 60161 (MO)
Kirra.jones@ahf.org
6255 W. Sunset Blvd., 21st floor
Los Angeles, CA 90028
Tel: 323-860-5200

KIM RILEY LAW
Andrew F. Kim, SBN 156533 (CA)
akim@kimrileylaw.com
Pro Hac Vice application to be filed
Rebecca J. Riley, SBN 139085 (CA)
rriley@kimrileylaw.com
Pro Hac Vice application to be filed
9018 Balboa Boulevard, #552
Northridge, CA 91325
Tel: 818 216-5288
Tel: 323-547-8992

Attorneys for Plaintiff
AIDS HEALTHCARE FOUNDATION